

Cerner Corporation

Methodologies for Automating Clinical Practice Guidelines

In 1991, healthcare expenditures in the United States were more than \$700 billion. Participants in the U.S. healthcare system, from patient to payer, recognized the importance of decreasing the cost of healthcare while improving its quality.

One initiative was the development of clinical guidelines, which many government agencies had undertaken. The guidelines incorporate best practices that address many different medical situations and have the potential to eliminate variations in treatment and the use of inappropriate procedures. Yet, by 1994, the guidelines were still used infrequently, in part because they were printed in thick handbooks, which made it difficult to quickly find information. Moreover, the guidelines were often too general for clinicians to use in specific situations.

Cerner Corporation, a leading U.S. provider of clinical and management information systems, planned to increase clinical guideline usage. Cerner estimated that if optimized clinical guidelines existed for almost all serious conditions and were implemented on a large scale in tools readily available in clinical practice, the United States could ultimately save billions of dollars in healthcare costs each year, while improving the quality of care. To increase the use of clinical guidelines, Cerner proposed to develop information tools, in collaboration with the University of Alabama at Birmingham and the Columbia-Presbyterian Medical Center. These tools would automate, validate, and distribute the guidelines for mass use. In 1994, as part of a focused program called "Information Infrastructure for Healthcare," Cerner received an award from the Advanced Technology Program (ATP) for a three-year project that began in 1995.

By the end of the project in 1997, Cerner had successfully developed information tools and a process for providing automated clinical guidelines to clinicians. However, the company was unable to commercialize the new technology after finding that clinicians were resistant to using the computer during the clinical process. Cerner has successfully used general concepts from the ATP-funded project to execute guidelines in its Cerner Millennium product. With Cerner Millennium, clinicians are electronically alerted about potential patient safety and regulatory issues through evidence-based medical information.

COMPOSITE PERFORMANCE SCORE

(based on a four star rating)

No Stars

Research and data for Status Report 94-04-0008 were collected during October 2003 – February 2004.

Clinical Practice Guidelines Are Infrequently Used

Clinical practice guidelines, which are carefully developed statements that incorporate the best practices in healthcare, can assist healthcare practitioners in making decisions on appropriate care for patients in specific clinical circumstances. The

guidelines have great potential to improve the quality of care by providing clinicians with current information that can be useful in many medical situations and by reducing variations in treatment and the use of inappropriate procedures. However, despite these benefits, clinical guidelines were infrequently used in the mid-1990s.

At that time, the guidelines were published in thick handbooks and were distributed to clinicians or were communicated through phone calls from case workers, commonly known in the health field as utilization reviewers. This made it difficult for the clinician to access relevant information at the time it was needed. Furthermore, the guidelines were often too general to apply to specific medical situations and, for the most part, had not been evaluated for their effect on patient treatment or acceptance by clinicians.

New Technology Could Automate Guidelines

Cerner Corporation, a leading provider of clinical and management information systems in the United States, recognized that in order to be useful, clinical guidelines had to be (1) available to the clinician when he or she was making a decision about a patient's treatment; (2) delivered within an integrated computer system; (3) applied to a patient's specific medical condition and associated with a clear, recommended course of action; and (4) evaluated for the results they produced and their acceptability to clinicians. According to Scott Siemers of Cerner, "The idea was to deliver the right information at the right time." To increase the use of clinical guidelines, Cerner proposed to develop an information infrastructure that would include the following:

- Methods for transferring written guidelines first to expert systems (software applications using a knowledge base of human expertise to aid in solving problems) then to healthcare professionals
- An effective computer-based architecture for implementing guidelines into a clinical practice. The system would be able to take guideline data and use it to provide to the clinician custom strategies and alternatives that were based on a specific patient's medical condition
- New coding structures that would package guidelines in automated, decision-support tools for use in different locations and situations
- Methods for testing the effectiveness of a guideline on practice patterns, quality of patient care, its safety, and its acceptability to clinicians

- A model for collecting and standardizing data from different systems, which would make it possible to evaluate and compare alternative treatments and interventions

At the same time that it developed the information infrastructure, Cerner would also develop guidelines for the new system. The company would identify topics that it believed could significantly improve laboratory medicine, would review and revise the written guidelines, would encode the guidelines, and would then deploy them in clinical practice. Finally, Cerner would evaluate the effectiveness of the guidelines and the deployment methodology.

Cerner believed that these changes would make a significant impact on the healthcare field. The infrastructure would include dynamic decision-support tools, which would lead to rational, repeatable medical care that could be evaluated. In the beginning of the project, Cerner would work only with laboratory medicine guidelines, but the methods could later be extended to other clinical domains.

Cerner Anticipates Broad-Based Benefits

Cerner believed that automated clinical guidelines had the potential to significantly improve healthcare in the United States. As guidelines became easier to access and apply to medical situations, they would be used more frequently, resulting in more standardized care based upon best practices. Moreover, the cost of healthcare would decrease as the number of hospital stays and complication rates declined and the morbidity and mortality rates decreased. The company estimated that if clinical guidelines were implemented on a large scale, savings in U.S. healthcare costs could amount to tens of billions of dollars per year.

Development of Automation Tool Suite Poses High Risk

Cerner understood that developing information tools and methodologies for automating, validating, and mass-distributing clinical practice guidelines was a high-risk endeavor. Introducing new technologies for automating standard guidelines into clinical settings would require meeting several technical challenges, such as determining how to build an infrastructure that could express certain elements of guidelines, like event sequences and flow charts, so that they could be used

by an expert system. Another challenge would be to identify the events that would trigger rule processing and the data elements needed for rule execution.

Because the project risks were more than Cerner could assume at the time, the company sought financial support from ATP in 1994. In the beginning of 1995, three-year funding was awarded as part of the ATP focused program, "Information Infrastructure for Healthcare." This support would allow the company to work to achieve all of its project objectives and would give Cerner the opportunity to ultimately commercialize the software and knowledge modules needed to automate clinical guidelines.

To obtain critical medical expertise, Cerner would collaborate with the University of Alabama at Birmingham (UAB) and the Columbia-Presbyterian Medical Center (CPMC). UAB would perform needs assessments and evaluations and would work with Cerner to select and evaluate implemented guidelines. CPMC had extensive experience creating medical logic modules for critiquing clinical practices and had led national efforts to introduce standard medical dictionaries, to transfer medical logic modules, and to encode guidelines. CPMC would provide a second evaluation site.

Cerner Develops New Technology for Automating Clinical Guidelines

Cerner's approach to meeting its goal of developing methodologies for automating, validating, and mass-distributing clinical practice guidelines followed a structured process. During the first year of the ATP-funded project, the company selected high-value guideline topics. For example, Cerner determined that blood transfusion and antibiotic selection presented good opportunities to make improvements. To clarify these topics further, the company focused on (1) the prevention of adverse events (this would improve patient care quality and reduce costs); and (2) order substitution (cases when a medication that is as effective and safe as another, but less expensive, could be substituted).

Next, Cerner developed a structure for presenting the guidelines to the clinician on the computer screen. The message would be displayed to the clinician in bullet style that used the fewest possible words. (Based on a customer concept test, the company believed that the message would have to be short and focused in order

to gain a physician's attention and encourage him or her to use the guideline.) The message structure would also permit queries, would suggest alternative actions, would provide hypertext explanations, and would allow the clinician to customize it. The guideline would also be delivered to the physician within one second of placing the order for a drug or procedure. Cerner believed that the guideline would have the greatest impact at this point.

Cerner believed that automated clinical guidelines had the potential to significantly improve healthcare in the United States.

By the end of the first year, Cerner had developed a prototype for a guideline product, Order Pro. It then formed an engineering team to develop solutions that would enable its already existing medical expert system, Discern Expert, to function with Order Pro and with the software used by physicians when placing an order for a drug or procedure.

In the second year of the project, Cerner focused on developing a consistent, high-quality process for authoring, reviewing, and disseminating the guidelines (now called "alerts," a name selected by Cerner to describe the cautionary nature of the guideline message). The company had learned in the previous year, through repeated trial and error, how difficult it was to write alerts. The alerts must significantly improve care delivery, and they must be specific enough to be encoded in a computer system. To assist with writing alerts, the company developed an author style guide, which it believed would set a new standard for knowledge transfer. The guide provided information on creating interactive alerts, actionable suggestions, and hypertext explanations. The company also worked to develop an internal and external peer review process for completed alerts that would meet the Food and Drug Administration's requirement for good manufacturing practices. Cerner decided to partner with Adis, a leading-edge New Zealand medical publishing company specializing in pharmacotherapy and pharmacoeconomics. Adis had the research and review mechanisms to create and update high-quality written materials. Adis also had an understanding of new markets and business processes, which would benefit Cerner.

Cerner created several prototypes of its new product. The first prototype, version 1.0, was completed in October 1996 and included the following features:

- Message display
- Interactive queries to narrow the context of an alert
- Selection of orders, with a recommendation that could easily be transferred to an order pad
- Ability to transfer information, regarding the action a physician took in response to an alert, to an action-tracking activity table

Engineering Problems with Second Prototype Delay Release

Cerner experienced significant engineering problems with the next prototype, version 1.1, and its release was delayed. This version included more complex features, such as the ability to trigger an alert from a laboratory order, forward a message to a clinician who was not logged into the system, recall the results of previous queries, and develop several action-tracking reports.

During the second year of the ATP project, Cerner worked on its marketing plan, which the company funded itself. Moreover, the company began to share its project-related knowledge with others in the healthcare field. Cerner spoke to the medical faculty at the Medical Center of Delaware about the company's efforts to develop and implement clinical guidelines for managing care. Presentations were also made to the MidWest Managed Health Care Congress about developing information management strategies to improve the delivery of patient care.

The alerts must significantly improve care delivery, and they must be specific enough to be encoded in a computer system.

By the third and final year of the ATP-funded project, Cerner had modified its goal to complete 100 Insights to completing 30. (Insights were previously called "alerts"; the name was changed to make the technology more appealing to physicians.) The company revised its goal because of both the complexity of writing each Insight and the high cost, which was estimated at between \$20,000 to \$30,000 for each Insight. One difficulty the company encountered was managing the number of exceptions to each Insight. Cerner found that the

number of exceptions increased the more the Insight was studied.

Cerner continued to build tools for clients that might want to create their own Insights. The company also completed a prototype of Discern Dialogue, an application that would enable a clinician to query the system about information delivered through an Insight. The prototype included functionality such as triggers for patient admissions, patient relocations, and laboratory results.

Clinicians Were Reluctant to Use New Technology

By the end of the ATP-funded project in 1997, Cerner had successfully developed an automated process for delivering clinical guidelines to healthcare professionals and, through several prototypes, had demonstrated that the process would work. The company planned to commercialize its new technology by licensing knowledge modules (50 to 75 Insights in a specific domain of medicine, such as drug-lab interactions or antibiotic utilization) on a subscription basis, for use within Cerner software systems.

To prepare for commercialization, the company conducted extensive market analyses, completed a business plan, pursued several technical and business alliances, prepared a market survey, showed its product concept to several potential clients, and trained its sales force. The company also gave several presentations on the new technology.

However, despite its marketing efforts, Cerner was unable to commercialize the new technology. Although the technology seemed promising to hospitals, many clinicians rejected the idea of using computers during the clinical process. They viewed the computer as an administrative device that would slow the clinical process.

ATP-Funded Project Results in Benefits

As of 2004, Cerner had not commercialized the technology it developed for automating clinical guidelines; however, the company had applied generalized concepts from this technology to implement Zynx guidelines and other evidence-based guidelines in the Cerner Millennium solutions. This solution integrates evidence-based content developed by Zynx Health (a former subsidiary of Cerner that evaluates

current scientific data) into an architecture used to structure, direct, and maintain clinical content as executable knowledge. Zynx has an extensive library of clinical “rules” and supporting evidence-based information regarding patient safety and regulatory compliance. This knowledge is used with an expert rules engine to electronically inform and alert clinicians about potential patient safety and regulatory issues. The solution is licensed to hospitals. In March 2004, Zynx Health was acquired by the Hearst Corporation.

Conclusion

With ATP’s assistance, Cerner developed information tools, medical content, and a process that could be used to provide best practices in healthcare to clinicians through automated clinical practice guidelines. At the end of the project, however, Cerner found that clinicians were reluctant to use computers, which they associated with administrative tasks, during the clinical process. Thus, the company was unable to commercialize the new technology. Since then, Cerner has successfully used general concepts from the ATP-funded project to execute guidelines in its Cerner Millennium product. With Cerner Millennium, clinicians are electronically alerted about potential patient safety and regulatory issues through evidence-based medical information.

PROJECT HIGHLIGHTS

Cerner Corporation

Project Title: Methodologies for Automating Clinical Practice Guidelines

Project: To develop information tools that automate, validate, and distribute clinical practice guidelines for clinician use.

Duration: 1/1/95-12/31/97

ATP Number: 94-04-0008

Funding (in thousands):

| | | |
|------------------------|------------|-----|
| ATP Final Cost | \$1,720 | 90% |
| Participant Final Cost | <u>193</u> | 10% |
| Total | \$1,913 | |

Accomplishments: ATP funding enabled Cerner to develop the technology to provide automated clinical practice guidelines to clinicians while they were providing treatment to a patient. Using this technology, clinicians could make informed decisions about appropriate healthcare for a patient based on his or her condition, history, and the best recommended practices. In addition to message display, the technology included features such as interactive queries, alerts to a clinician based on a laboratory order, and action-tracking reports.

Cerner shared its project-related knowledge through the following publications and presentations:

- Cerner Annual Healthcare Conference. 1995, 1996, and 1997. (Presentations).
- Jamieson, Patrick, M.D. "Computer and Information Technology in the Health Field." Conference Presentation, Saudi Arabia, 1995.
- Jamieson, Patrick, M.D. "Developing and implementing clinical guidelines for managing care." Speech to Medical Center of Delaware, 1996.
- Jamieson, Patrick, M.D. "Developing information management strategies to improve the delivery of patient care." Speech to Midwest Managed Health Care Congress, 1996.
- Healthcare Information and Management Systems Society Conference, 1997 (Presentation).

- Healthcare Information and Management Systems Society Conference Proceedings, 1997 (Publication).

Commercialization Status: Cerner did not commercialize its technology for automating clinical practice guidelines. In 1997, when the ATP-funded project ended, clinicians were reluctant to use computers during the clinical process. In 1998 and 1999, hospitals were focused on meeting Year 2000 requirements and did not want to implement new technology. Cerner continued its marketing efforts until after 2001, but was not successful. However, the company has since been able to apply the knowledge it gained from the ATP-funded project to its Cerner Millennium solution, an automated medical information system that alerts clinicians about potential patient safety and regulatory issues.

Outlook: Since 1997, other companies, such as IDX Systems, 3M, and Eclipsys, have been using technology similar to that developed by Cerner for automating clinical practice guidelines. These technologies include features such as order entry and insights. As of 2004, Cerner plans to use general concepts from the ATP-funded project to execute guidelines in its Cerner Millennium product.

Composite Performance Score: No Stars

Focused Program: Information Infrastructure for Healthcare, 1994

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